IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ANDREA PERRY and GEORGE PERRY, both individually and as next friends of ANDREAS PERRY, a minor, Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION, NOVARTIS PHARMA GMBH, NOVARTIS AG, JAE A. SPARKS and MARY GIANSTASIO, Defendants.	§	**ELECTRONICALLY FILED** Civil Action No.: 05-cv-05350

PLAINTIFFS' SECOND AMENDED COMPLAINT

Plaintiffs, Andrea Perry, George Perry and Andreas Perry, by and through counsel, and for their Complaint against the Defendants, state:

PARTIES

1. Plaintiff, Andrea Perry, is a resident and citizen of Coatesville, Chester County, Pennsylvania, and the next friend of Plaintiff Andreas Perry.

2. Plaintiff, George Perry, is a resident and a citizen of Coatesville, Chester County, Pennsylvania, and the next friend of Plaintiff, Andreas Perry.

3. Plaintiff, Andreas Perry, a minor, is a resident and citizen of Coatesville, Chester County, Pennsylvania.

4. Defendant, Novartis Pharmaceuticals Corporation ("NPC") is a corporation incorporated under the laws of Delaware with its principal place of business located at 59 Route 10, East Hanover, New Jersey, 07936-1080. Defendant is registered with the Pennsylvania

Department of State, Division of Corporations and authorized to conduct business in Pennsylvania as a foreign for-profit corporation. Service of process may be made on NPC by serving its designated registered agent, Secretary of State, Corporations Division.

5. Defendant, Novartis Corporation ("Novartis Corp.") is a corporation incorporated under the laws of New York with its principal place of business located at 180 Park Avenue, Florham Park, New Jersey, 07932. Novartis Corporation is the North American headquarters of Swiss Novartis. Service of process may be made on Novartis Corp. by serving its designated registered agent, Secretary of State, Corporations Division.

6. Defendant, Novartis Pharma GmbH (hereinafter "GmbH"), is a German corporation doing business in the United States, and Pennsylvania specifically, through its agent, subsidiary or alter-ego NPC and/or Novartis Corp. GmbH will be served with process through the Hague Convention on Service of Process Abroad of Judicial and Extra-Judicial Documents in Civil and Commercial Matters.

7. Upon information and belief, Defendant, GmbH, is the ultimate physical manufacturer of the product in question and does so with the intent to sell, provide, distribute, supply or place in the stream of commerce either directly or indirectly through, Novartis Corp. and/or NPC, for ultimate use by consumers throughout the United States and the Commonwealth of Pennsylvania. Defendant, GmbH, is listed as the manufacturer on all packaging, labeling, product inserts, and patient information sheets provided to physicians and consumers in the United States and Pennsylvania.

8. Defendant, Novartis AG (hereinafter "NAG"), is a Swiss corporation doing business in the United States, and Pennsylvania specifically, through its agent, subsidiary or alter-ego NPC, Novartis Corp., GmbH and/or Sales Representative Defendants, and is publicly

traded on the New York Stock Exchange. NAG will be served with process through the Hague Convention on Service of Process Abroad of Judicial and Extra-Judicial Documents in Civil and Commercial Matters.

9. NAG, directly and indirectly, owns a 100% interest in NPC, Novartis Corp and GmbH. NAG is ultimately responsible for the organization, administration and direction of NPC and Novartis Corp, and determines the companies' strategies. NAG is also the patent holder of pimecrolimus and trademark holder of the word "ELIDEL" here, in the United States.

10. Upon information and belief, members of the Board of Directors of NPC and/or Novartis Corp., sit on the Novartis Executive Committee which develops and implements strategies for the Novartis Group[1] and procures and allocates the required resources.

11. As used herein, the term "Novartis Defendants" refers collectively to Defendants, Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis Pharma GmbH and Novartis AG.

12. At all times material hereto, Novartis Defendants, either collectively or individually, designed, tested fabricated, formulated, processed, manufactured, distributed, marketed and sold the drug pimecrolimus, trademarked and marketed as Elidel, in Pennsylvania for purposes of treating various skin diseases.

13. Novartis Defendants have substantial contacts and a presence in Pennsylvania including, but not limited to the fact that its employees, agents, sales representatives and/or independent contractors are citizens within Pennsylvania who are paid by Novartis Defendants,

[1] The "Novartis Group" refers to the ultimate parent company, Novartis AG and its some 360 affiliates in 140 countries.

to act on their behalf, and who have power and authority to legally bind and obligate both companies to contracts and the laws of Pennsylvania.

14. Defendant, Jae A. Sparks ("Sparks"), is a citizen of Pennsylvania. At all times material hereto, Defendant held himself out as a sales representative, employee, agent and/or detail person of Novartis Defendants for purposes of marketing, distribution, providing product information and giving out samples of pimecrolimus, to healthcare provides, including to Plaintiffs' treating physician, in the Commonwealth of Pennsylvania.

15. Sparks also held himself out as a person with technical and specialized knowledge about pimecrolimus, for which he expected healthcare providers, including Plaintiffs' treating physician, to rely upon what he said and represented about pimecrolimus. Sparks, as a sales representative/detail person of Novartis Defendants, played a vital role in the distribution and marketing of pimecrolimus. He was a conduit for the technical and medically related information given to healthcare providers, including Plaintiffs' treating physician. Sparks also had a direct financial interest in the sale of pimecrolimus, since he was eligible for commissions based on the number of prescriptions written for pimecrolimus.

16. In his capacity as an employee, sales representative, agent, and/or detail person, Sparks had as his job responsibilities to meet with healthcare providers authorized to treat patients in Pennsylvania, including Plaintiffs' treating physician for the express purpose of distributing, marketing, providing warnings, product information and making representations about the safety of pimecrolimus. In addition, Spark's job responsibilities and actions were intended to be an integral part of the distribution and marketing of pimecrolimus to healthcare providers by making representations and persuading them to write prescriptions on behalf of their patients in treatment of certain skin diseases. Finally, Sparks on a regular basis distributed

and supplied healthcare providers, including Plaintiffs' treating physician, with substantial quantities of pimecrolimus samples with the expectation that they would be given cost-free to patients like Plaintiff, Andreas Perry, in an effort to increase sales, prescriptions, use and exposure to the drug.

17. Defendant, Mary Gianstasio ("Gianstasio"), is a citizen of Pennsylvania. At all times material hereto, Defendant held herself out as a sales representative, employee, agent and/or detail person of Novartis Defendants for purposes of marketing, distribution, providing product information and giving out samples of pimecrolimus, to healthcare provides, including to Plaintiffs' treating physician, in the Commonwealth of Pennsylvania.

18. Gianstasio also held herself out as a person with technical and specialized knowledge about pimecrolimus, for which she expected healthcare providers, including Plaintiffs' treating physician, to rely upon what she said and represented about pimecrolimus. Gianstasio, as a sales representative/detail person of Novartis Defendants, played a vital role in the distribution and marketing of pimecrolimus. She was a conduit for the technical and medically related information given to healthcare providers, including Plaintiffs' treating physician. Gianstasio also had a direct financial interest in the sale of pimecrolimus, since she was eligible for commissions based on the number of prescriptions written for pimecrolimus.

19. In her capacity as an employee, sales representative, agent, and/or detail person, Gianstasio had as her job responsibilities to meet with healthcare providers authorized to treat patients in Pennsylvania, including Plaintiffs' treating physician, for the express purpose of distributing, marketing, providing warnings, product information and making representations about the safety of pimecrolimus. In addition, Gianstasio's job responsibilities and actions were intended to be an integral part of the distribution and marketing of pimecrolimus to healthcare

providers, including Plaintiffs' treating physician, by making representations and persuading them to write prescriptions on behalf of their patients in treatment of certain skin diseases. Finally, Gianstasio on a regular basis distributed and supplied healthcare providers, including the Plaintiffs' treating physician, with substantial quantities of pimecrolimus samples with the expectation that they would be given cost-free to patients like Plaintiff, Andreas Perry, in an effort to increase sales, prescriptions, use and exposure to the drug.

20. As used herein, Jae A. Sparks and Mary Gianstasio, shall be referred to collectively as "Sales Representative Defendants."

JURISDICTION

21. The Court has jurisdiction over the lawsuit under 28 U.S.C. §1332 because the plaintiffs and the defendants are citizens of different states, and the amount in controversy exceeds $75,000.00, exclusive of interests and costs.

22. NPC is subject to the jurisdiction of Pennsylvania in that this defendant committed tortious acts within the State. NPC is further subject to jurisdiction in Pennsylvania based upon, but not limited to, transactions in Pennsylvania causing tortious injury to the Plaintiffs, and by their acts or omissions occurring outside Pennsylvania but injuring Plaintiffs within Pennsylvania. Further, NPC engaged in or solicited business within Pennsylvania from which they derived substantial revenue from pimecrolimus, being sold, prescribed and used in Pennsylvania.

23. Novartis Corp. is subject to the jurisdiction of Pennsylvania in that this defendant committed tortious acts within the State. Novartis Corp. is further subject to jurisdiction in Pennsylvania based upon, but not limited to, transactions in Pennsylvania causing tortious injury

to the Plaintiffs, and by their acts or omissions occurring outside Pennsylvania but injuring Plaintiffs within Pennsylvania. Further, Novartis Corp engaged in or solicited business within Pennsylvania, either directly or through its agent Defendant, NPC, and/or Sales Representative Defendants, from which they derived substantial revenue from pimecrolimus, being sold, prescribed and used in Pennsylvania.

24. Pursuant to 42 Pa.C.S. § 5322 (2005) GmbH and NAG are subject to personal jurisdiction in Pennsylvania. GmbH and NAG, either directly or through its agents and/or alter-egos, NPC, Novartis Corp., and/or Sales Representative Defendants, designed, manufactured, formulated, prepared, tested, processed, distributed, marketed and sold pimecrolimus with the expectation that said product would be distributed, sold, marketed, prescribed and used in Pennsylvania. In addition, they had the expectation that pimecrolimus would in fact be distributed, marketed, sold, prescribed and ultimately used by consumers in Pennsylvania. As a result, GmbH and NAG have derived substantial income, revenue, and profits from Elidel sales within Pennsylvania.

FACTUAL BACKGROUND

DRUG LABELING

25. Prescription drug labeling is required, among other things:

A. To contain a summary of the essential scientific information needed for the safe and effective use of the drug (21 C.F.R. §201.56(a))[Effective until June 30, 2006.];

B. To be informative and accurate and neither promotional in tone nor false or misleading in any particular (21 C.F.R. §201.56(b))[Effective until June 30, 2006];

C. To be based whenever possible on data derived from human experience

(21 C.F.R. § 201.56(c))[Effective until June 30, 2006] ; and

D. To contain specific information under various section headings, including Description, Clinical Pharmacology, Indications and Usage, Contraindications, Warnings, Precautions, Adverse Reactions, Drug Abuse and Dependence, Overdosage, Dosage and Administration, and How Supplied. (21C.F.R. §201.56(d)(1))[Effective until June 30, 2006.]

26. The Warnings section heading listed in Section 201.56 [d] is required to describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. (21 C.F.R. §201.57(e))[Redesigned as §201.80 at 71 FR 3922, 3988, Jan. 24, 2006, effective June 30, 2006.]

27. The Warnings section heading listed in Section 201.56 [d] is required to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug, and a causal relationship need not have been proved. (21 C.F.R. §201.57(e))[Redesigned as §201.80 at 71 FR 3922, 3988, Jan. 24, 2006, effective June 30, 2006.]

28. The Warnings section of the labeling shall identify any potentially fatal adverse reactions. (21 C.F.R. §201.57(g)(3))[Redesigned as §201.80 at 71 FR 3922, 3988, Jan. 24, 2006, effective June 30, 2006.]

29. The Warnings section heading listed in Section 201.56 [d] may be required by the Food and Drug Administration to include special problems, particularly those that may lead to death or serious injury, to be placed in a prominently displayed box. This prominently displayed box is commonly referred to as the "Black Box Warning". (21 C.F.R. §201.57(e))[Redesigned as §201.80 at 71 FR 3922, 3988, Jan. 24, 2006, effective June 30, 2006.]

30. The Black Box Warning shall contain the frequency of these serious adverse

reactions and, if known, the approximate mortality and morbidity rates for patients sustaining the reactions, which are important to safe and effective use of the drug, and shall be expressed as provided under the "Adverse Reactions" section of the labeling. (21 C.F.R. §201.57(e))[Redesigned as §201.80 at 71 FR 3922, 3988, Jan. 24, 2006, effective June 30, 2006.]

31. An Adverse Reaction is an undesirable effect, reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence. (21 C.F.R. §201.57(g))[Redesigned as §201.80 at 71 FR 3922, 3988, Jan. 24, 2006, effective June 30, 2006.]

32. The Adverse Reaction section shall list the adverse reactions that occur with the drug and with drugs in the same pharmacologically active and chemically related class. (21 C.F.R. §201.57(g)(1))[Redesigned as §201.80 at 71 FR 3922, 3988, Jan. 24, 2006, effective June 30, 2006.]

33. Adverse Reactions that are significantly more severe than the other reactions listed in a category shall be listed before those reactions, regardless of its frequency. (21 C.F.R. §Section 201.57(g)(2))[Redesigned as §201.80 at 71 FR 3922, 3988, Jan. 24, 2006, effective June 30, 2006.]

THE MEDICATION

34. NAG holds United States Patent number 5,912,238 for the substance known as pimecrolimus, which was developed as a topical immunosuppressant. In its patent application NAG cited to the patent application for the substance, tacrolimus, as supporting documentation.

35. Pimecrolimus is a macrolide lactone antibiotic, initially developed under the name

SDZ ASM 981 by Sandoz[2], and is the ethyl analog of another macrolide, tacrolimus. It was isolated from Streptomyces hygroscopius var. ascomyceticus (Ascomycin) and can also be derived from Streptomyces Tsukubaensis.

36. Pimecrolimus like tacrolimus, binds strongly to macrophilin-12 (FKBP-12) and also inhibits the calcium-dependent phoshatase called calcineurin. This binding results in inhibition of T cell activation by blocking the transcription of early cytokines. Both pimecrolimus and tacrolimus prevent the release of inflammatory cytokines and mediators from mast cells after stimulation by antigen/IgE and inhibit calcineurin. Hence the drugs are also known as calcineurin inhibitors.

37. The United States Adopted Names Council (USAN), which is the national organization that assigns generic names. USAN has assigned both drugs the stem "imus" to their generic names. This indicates that USAN has concluded that these two drugs have similar pharmacological and/or chemical relationship. Thus, putting pimecrolimus and tacrolimus in the same drug classification as each other. When healthcare professionals such as physicians and pharmacists see the same stem "imus", they make the relationship that the two drugs are in the same pharmaceutical class, work in the body similarly, and have similar side effects.

FROM NDA TO "BLACK BOX"

38. On December 13, 2001, Novartis Defendants received Food and Drug Administration ("FDA") approval of its NDA for pimecrolimus, for the treatment of atopic dermatitis. The product had limited prescribing restrictions for its use and application including, for example, that it should not be prescribed for long term use and that it should only be used as

[2] In 1996 Ciba-Geigy, Ltd. merged with Sandoz Pharmaceuticals Corporation, Sandoz AG and Sandoz Pharma AG to form Novartis AG and its progeny. All documents related to the development and testing of SDZ ASM 981 thus were acquired by NAG and its progeny.

a second-line therapy only after first-line treatments were ineffective or could not be used.

39. Eczema is the clinical name for dermatitis, or "[s]uperficial skin inflammation, characterized histologically by epidermal edema and clinically by vesicles (when acute), poorly marginated redness, edema, oozing, crusting, scaling, usually pruritus, and lichenification caused by scratching or rubbing." The Merck Manual of Diagnosis and Therapy 786 (Mark H. Beer, M.D. et al eds., 17th ed. 1999).

40. Prior to the approval of topical preparations of theses drugs, calcineurin inhibitors had been approved for use as systemic immunosuppressants in organ transplant recipients. In these patients, systemic treatment has long been known to increase the risk of malignancies and have carried appropriate Black Box Warnings.

41. No later then December 2001, the Novartis Defendants knew the FDA was concerned of the potential for pediatric patients to develop systemic malignancies with intermittent use of pimecrolimus. The FDA expressed this concern in their approval letter to the Novartis Defendants.

42. Because of these various concerns, the approval of pimecrolimus for treatment of atopic dermatitis in children included a post-marketing commitment from Novartis Defendants to conduct a registry study to asses the risk for developing cutaneous or systemic malignancies among pediatric patients who undergo intermittent treatment with these drugs.

43. On October 30, 2003, an open meeting of the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee was held to discuss how to approach long-term monitoring for malignancy occurrence, among patients treated for atopic dermatitis with pimecrolimus and tacrolimus.

44. The subcommittee noted that the preclinical and clinical studies of both

pimecrolimus and tacrolimus suggested these drugs may increase the risk of malignancies in the pediatric population.

45. The subcommittee further stated that for children under 2; because of immune system development issues and lack of understanding regarding the development of other systems in the very young, a Black Box Warning was recommended but never implemented.

46. Following the close of the October 2003 subcommittee meeting, the adverse events relating to pimecrolimus and tacrolimus continued to increase. Specifically, there were additional malignancy cases that had been reported to the FDA.

47. Based on this concern the Pediatric Advisory Committee of the FDA convened, on February 14 & 15, 2005 again to discuss the potential malignancy risk from the use of pimecrolimus and tacrolimus.

48. In March 2005, after accumulating scientific evidence of deaths, malignancies and other serious adverse events the FDA required Novartis Defendants to require a Black Box Warning of malignancy risks on pimecrolimus.

49. In January 2006, the language to be included in the above mentioned Black Box was finally agreed to by and between the Novartis defendants and the FDA, and thereafter the Black box Warning was affixed to the pimecrolimus label.

THE NOVARTIS DEFENDANTS

50. From 2001 through the date of this complaint, the Novartis defendants generally, GmbH and NPC specifically, manufactured, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part and parcel to the sale and distribution of a pharmaceutical, and by said activities, caused pimecrolimus to be placed into the stream of commerce throughout the United States, including the Commonwealth of

Pennsylvania.

51. The Novartis defendants, made, participated in and/or contributed to filings with the FDA in conjunction with the approval process for pimecrolimus in the United States. As part of said activities, the Novartis defendants also engaged in "negotiations" with the FDA with respect to the approval of the labeling, (also known as the "package insert" or "direction circular" to be approved for use with pimecrolimus).

52. The Physician's Desk Reference ("PDR") contains the information from the product labeling as provided by the drug manufacturer.

53. Upon information and belief the plaintiffs allege that the Novartis defendants, individually and collectively, were in control of the design, assembly, manufacture, marketing, distribution, packaging, labeling, processing, supplying, promotion, sales, and the issuance of product warnings and related information with respect to pimecrolimus.

54. Pimecrolimus has been widely advertised, marketed and represented by the defendants as a safe and effective treatment for atopic dermatitis or eczema.

55. The Novartis defendants were at all times material hereto subject to the laws of the United States of America, including provisions relating to the FDA, and the rules and regulations thereof, in conjunction with the approval process, labeling, and other after market activities that pertain to all pharmaceuticals, including pimecrolimus.

56. Upon information and belief, the plaintiffs allege that pimecrolimus causes injury, including but not limited to malignancies and other serious health problems.

57. To promote pimecrolimus and to increase the total market and sales of the drug, the Novartis defendants hired public relations, marketing, and advertising firms, provided promotional materials to sales forces, sponsored studies, hired ghost writers to publish papers in

medical journals that supported the use of pimecrolimus, provided media contacts with promotional material, and in essence engaged in a widespread plan to market the use of pimecrolimus, thereby increasing sales and enlarging the market potential for pimecrolimus.

58. In part due to the promotional efforts of the Novartis defendants, pimecrolimus was so pervasively prescribed throughout the United States that, by 2005, the number of prescriptions in the United States totaled in the millions.

59. As early as 2001, and up through and including 2005, the package insert for pimecrolimus failed to provide any WARNINGS for malignancies in association with the use of pimecrolimus.

60. In fact, Novartis defendants had known at all times material, that physicians more often read the WARNINGS portion of the PDR rather than any other section, and certainly much more often than they read the PRECAUTIONS section.

61. As early as 2001, and up through and including 2005, absolutely no information regarding malignancies had ever been included in the WARNINGS section of the product labeling for pimecrolimus. In fact no information regarding malignancies whatsoever was provided in the PRECAUTIONS section of the PDR either.

62. The Novartis defendants also knew that because both pimecrolimus and tacrolimus belonged to the same class of drugs, i.e. calcineurin inhibitors, that any adverse event applicable to one would be applicable to the other.

63. Despite their knowledge of the potentially life threatening diseases associated with increased use of their pimecrolimus, the Novartis defendants engaged in a marketing and advertising program, which as a whole, by affirmative and material misrepresentations and omissions, falsely, fraudulently, and criminally sought to create the image and impression that

the use of pimecrolimus was safe for human use, had fewer side effects and adverse reactions than other methods of treating eczema, and would not result in a side effect that was potentially fatal.

64. The Novartis defendants falsely and fraudulently kept relevant information from prescribing physicians and potential pimecrolimus users in order to minimize user and prescriber concern regarding the safety of the drugs.

65. The Novartis defendants, individually and collectively, purposefully downplayed and understated the health hazards and risks associated with the use of pimecrolimus, and, through promotional literature as well as sales visits to prescribing physicians, deceived prescribing physicians and potential users of pimecrolimus by relaying positive information, and manipulating statistics to suggest widespread acceptability, while concealing the nature and extent of known adverse and serious health effects.

66. The information produced and disseminated by and on behalf of the Novartis defendants, falsely and fraudulently misrepresented a number of facts regarding pimecrolimus, including, but not limited to, the existence of adequate testing of pimecrolimus, and the nature, severity, and frequency of side effects and adverse health effects caused by pimecrolimus.

67. Prior to January 19, 2006, no WARNINGS were listed in the pimecrolimus listing in the various PDR's in effect during the pre-market period, up to the publication and distribution of the 2005 issue, and the initial product labeling for pimecrolimus, to alert prescribing physicians as well as consumer patients of the actual risks associated with this drug, including the risk of potentially fatal malignancies, and the extent or actual risk thereof, notwithstanding the fact that the Novartis defendants, individually and collectively, knew that reasonable evidence of an association between the use of pimecrolimus and such conditions

existed.

68. The Novartis defendants were acutely aware of how physicians reacted to what was included in the product labeling, how the labeling would impact upon physician's prescribing patterns, and the methods that could be employed to minimize physician awareness of certain side-effects or to make such side-effects more readily apparent to the reader of the labeling. In fact, the Novartis defendants knew that physicians paid much closer attention to the WARNINGS section of product labeling than any other section. Also information contained in the WARNINGS section, and the manner and method of how it was displayed ultimately affected the physician's willingness to prescribe the pharmaceutical, in this case, pimecrolimus.

69. The Novartis defendants, individually and collectively, notwithstanding access to information establishing the aforementioned dangers associated with the use of pimecrolimus specifically and, immunosuppressants generally, promoted the use of pimecrolimus as an effective treatment for eczema without offering timely supplements to their warnings and product information to fully, completely and/or adequately advise prescribing physicians and potential consumers of the very real risks and side effects, especially that of malignancies.

70. The Novartis defendants failed to timely and appropriately amend, change, alter or otherwise update the product labeling, package insert, or to otherwise advise physicians, patients, pharmacists, or other health care providers of the risk of developing malignancies, and intentionally hid the data and information regarding the aforementioned danger associated with the use of pimecrolimus, for the sole and exclusive purpose of ensuring that their product, would be approved by the FDA, and ultimately increase profits of the Novartis defendants.

71. Nevertheless, the Novartis defendants negligently and intentionally failed to fully or adequately warn and apprize prescribing physicians, as well as the consumer public, including

the plaintiff, Andreas Perry, and his physicians, that there was any risk of developing malignancies.

72. In addition, the Novartis defendants failed to adequately or completely warn the prescribing physicians and the consumer public, including the plaintiff, Andreas Perry, about the special risks of developing malignancies (and other problems) associated with pimecrolimus, of which use the said defendants, individually and collectively, were well aware.

73. Furthermore, the Novartis defendants knew about the malignancies associated with immunosuppressants such as pimecrolimus *even before* they did the first test on a rat for their investigational new drug application to the FDA, by virtue of their experience with similar drugs in organ transplant patients, and similar topical immunosuppressants/calcineurin inhibitors already on the worldwide market.

74. As a direct and proximate result of the failures of the Novartis defendants to fully, completely, adequately and appropriately disclose the aforesaid information to prescribing physicians in the United States, including the Commonwealth of Pennsylvania, physicians had been prescribing and over-prescribing pimecrolimus to patients, and both prescribing physicians and the consumer public, including the plaintiff, Andreas Perry, had been grossly under-informed regarding the risks of serious health effects, including malignancies, which were clearly reported and/or known to be associated with immunosuppressant drugs.

75. Despite knowing of an increased incidence of malignancies beyond what was reported to physicians in product labeling and in the PDR, and the Novartis defendants enjoying markedly increased sales of pimecrolimus, the said defendants consciously and with full knowledge and intent, deprived the general public and physicians of such knowledge. In fact, the Novartis defendants, through an intentional lack of action knowingly decided not to include

Warnings of adverse events regarding malignancies, or to send physicians any "Dear Doctor" letters, or to otherwise alert the health care profession, for fear that it could limit the growth potential of the drug.

FACTUAL ALLEGATIONS – ANDREAS PERRY'S CASE

76. Prior to May 2003, the treating physician as well as the Plaintiff's mother, Andrea Perry, were exposed to the aforementioned advertising and marketing campaign directly by the Defendants and became interested in pimecrolimus, more commonly known as Elidel.

77. The plaintiffs' physicians and mother, Andrea Perry, either through direct promotional contact with Sales Representative Defendants, through word of mouth from other health care providers, or through promotional materials, received the information the Defendants intended that they receive, to-wit: that Elidel was "steroid-free," safer then corticosteroids, had very little side effects and could be used as first-line therapy.

78. Having heard of Elidel as a safer alternative for the treatment of eczema, on or about April 30, 2003, the plaintiff's mother presented her child, Plaintiff, Andreas Perry, to a physician for the purposes of treating her son's eczema. At that time, the physician performed a physical examination which found the plaintiff, Andreas Perry, to be suffering from eczema. The plaintiff's mother was given samples of Elidel and directed to apply the topical as indicated.

79. As a direct and proximate result of the use and application of pimecrolimus, Plaintiff, Andreas Perry, suffered serious bodily injury and harm, including being diagnosed with a malignancy, more specifically lymphoblastic lymphoma.

80. At no time material to his use of pimecrolimus, was Plaintiff, Andreas Perry, told, warned or given information about the risks of developing malignancies caused by the use

of pimecrolimus.

81. As a result of the aforementioned acts and conduct, the Plaintiff, Andreas Perry, has suffered grievous personal harm and related damages.

Discovery Rule and Fraudulent Concealment

82. The nature of Plaintiff, Andreas Perry's, injuries and their relationship to pimecrolimus use were inherently undiscoverable; and, consequently, the discovery rule should be applied to the running of the statute of limitations. The causes of action arising from Andreas Perry's usage of pimecrolimus did not and could not have accrued prior the date of his injury because Plaintiffs did not know and could not have known through the exercise of reasonable care and diligence of the existence of Plaintiffs' claims against Defendants.

83. Further, prior to the date of Andreas Perry's injuries, Plaintiffs did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct. Under appropriate application of the "discovery rule," Plaintiffs' suit was filed within the applicable statutory limitations period because Plaintiffs filed this lawsuit within two (2) years from the date of Plaintiffs' discovery of the cause of their son's injury and their damages.

84. Moreover, Defendants fraudulently concealed from Plaintiffs the nature of the injury and the connection between the injury and pimecrolimus.

Count I – Deceit and Fraud
By Novartis Defendants

85. Plaintiffs incorporate herein by reference and re-assert the allegations contained in paragraphs 1-84 above.

86. As early as 1999, Novartis Defendants had specific knowledge about serious

adverse events, reactions, defects, health risks, unreasonable and inherent dangers and consequences posed by the use and application of pimecrolimus, including the development of malignancies. These dangers and health risks were known by Novartis Defendants based upon scientific evidence, their own research, post-marketing adverse events, clinical studies, animal studies, and secret studies conducted which were not made public. Despite possessing this knowledge, Novartis Defendants intentionally misrepresented the safety of pimecrolimus, by representing the drug did not impose any undue, inherent or serious health risks to persons who were prescribed the product and/or given samples by their healthcare providers.

87. Additionally, Novartis Defendants intentionally misrepresented the safety of pimecrolimus, through its product brochures, product inserts, information and by oral presentations made by its employees to Plaintiffs' treating physician.

88. These misrepresentations about the safety and efficacy of pimecrolimus, included the fact that the drug did not pose any unreasonable or inherent health risks to patients to whom it was prescribed or given samples; being steroid-free it was completely safe, and safer than topical corticosteroids; there was no risk of malignancy associated with the use and application of pimecrolimus; and it was safe to be used as a first-line therapy of treatment when in fact the drug was only intended to be a second-line therapy.

89. Despite the knowledge of Novartis Defendants to the contrary, they misrepresented information both orally and in writing to healthcare providers, including Plaintiffs' treating physician, about the safety of the product. Novartis Defendants intentionally misrepresented pimecrolimus as safer than topical corticosteroids, for the express purpose of having physicians, including Plaintiffs' treating physician, prescribe the product and give out samples. Novartis Defendants intentionally misrepresented to healthcare providers the lack of

serious health and malignancy risks resulting from the use and application of pimecrolimus, knowing there would be reliance on these misrepresentations in making decisions on prescribing pimecrolimus.

90. These misrepresentations by Novartis Defendants were material in that they involved statements about the safety and efficacy associated with pimecrolimus. Novartis Defendants intended that treating healthcare physicians, including Plaintiffs' treating physician, would rely on these misrepresentations which they knew to be false, or which were made in a reckless manner.

91. Novartis Defendants intentionally failed to inform Plaintiffs regarding the fact that clinical trials conducted by Novartis Defendants showed an increased risk of malignancies with the use of pimecrolimus.

92. Since the beginning of their marketing campaign and in April 2003 when pimecrolimus, was given to Plaintiff, Andreas Perry, Novartis Defendants made material misrepresentations that the drug had been clinically and laboratory tested and medically proven safe. As set forth above, Novartis Defendants misrepresented that their product was appropriate as a first-line therapy and that it was safe, effective, and well tolerated for patients such as Plaintiff, Andreas Perry, when in fact it was not. At the time the misrepresentations were made to Plaintiffs in April 2003 upon Plaintiffs' initial use of pimecrolimus, they were false and Novartis Defendants knew they were false.

93. Plaintiffs reasonably relied upon such representations in deciding to begin using Novartis Defendants' product in April 2003 and, but for such representations of safety and appropriateness, they would not have used it.

94. Specifically, Plaintiffs were informed and told, through their treating physician,

as the conduit for Novartis Defendants that pimecrolimus was a safer alternative to corticosteroids and safe to use as a first-line therapy for their child's skin condition. In April 2003, Plaintiffs were given samples of pimecrolimus. No information regarding any serious adverse events or other serious risks associated with pimecrolimus were relayed to Plaintiffs.

95. Upon information and belief, Novartis Defendants, were aware that malignancies were identified as a serious adverse event for pimecrolimus, as early as 1999.

96. Despite possessing such knowledge, Novartis Defendants marketed the product without a warning from the beginning of its marketing campaign and in April 2003, when pimecrolimus, was first given to Plaintiff.

97. As stated above, this omission was material and induced Plaintiffs to use Novartis Defendants' product. If they had been told that pimecrolimus could cause malignancies, they would have been in better position to make a more fully informed decision to use or not use the product.

98. The misrepresentations and omissions set forth above were done with the knowledge that the misrepresentations were false when made.

99. As a direct and proximate result of the intentional misrepresentations as set forth above, Plaintiffs applied pimecrolimus, to their infant son which ultimately resulted in his diagnosis of Lymphoblastic Lymphoma.

100. As a direct and proximate result of Novartis Defendants' deceit and fraud, Plaintiffs have sustained serious and permanent injuries, including but not limited to, damages, pain and suffering, emotional distress, fear of future diseases, psychological injuries, physical disfigurement, scarring, loss of the enjoyment of life, and risks of reoccurrence of malignancies. Plaintiffs have further incurred medical bills and other healthcare expenses. Plaintiff, Andreas

Perry's, physical and emotion injuries, serious adverse events and other health problems proximately caused by the use and application of pimecrolimus, are permanent and continue to compromise, diminish and suppress his natural immune system which exposes him to further health problems, physical ailments, and serious adverse events.

101. In that the injuries suffered by the Plaintiff, Andreas Perry, are continuing in nature, he will continue to suffer, pain, psychological and emotional injuries, physical handicap and permanent injury in the future, will be further compelled to expend great sums of money for medical care and related treatment for said injuries, and will continue to suffer loss or impairment of the capacity for the enjoyment of life.

WHEREFORE, Plaintiffs claim of Novartis Defendants, compensatory damages, punitive damages, interest and allowable costs of suit.

Count II – Fraud and Deceit
Against Jae A. Sparks and Mary Gianstasio

102. Plaintiffs incorporate herein by reference and re-assert the allegations contained in paragraphs 1-84 above.

103. No later then April 2003, Sales Representative Defendants, knew or should have known about serious adverse events, reactions, defects, health risks, unreasonable and inherent dangers and consequences posed by the use and application of pimecrolimus, including the development of malignancies.

104. These dangers and health risks were known by the Sales Representative Defendants based upon scientific evidence, research, post-marketing adverse event, clinical studies, animal studies, and secret studies conducted by Novartis Defendants, relayed to the Sales Representative Defendants which were not made public.

105. Despite possessing this specialized knowledge, the Sales Representative Defendants, intentionally misrepresented the safety of pimecrolimus by representing the drug did not impose any undue, inherent or serious health or safety risks to persons who were prescribed the product and/or given samples by a healthcare provider.

106. Upon information and belief, the Sales Representative Defendants intentionally misrepresented the safety of pimecrolimus through the distribution of product brochures, product inserts, information, and by oral presentations about the product's safety made to Plaintiffs' treating physician and Plaintiff, Andrea Perry, herself, which the Sales Representative Defendants knew not to be true.

107. These misrepresentations about the safety of pimecrolimus included that the drug did not pose any unreasonable or inherent health risks to patients to whom it was prescribed or given samples; being steroid-free it had no safety risks and was safer than topical corticosteroids; there was no risk of malignancies associated with the used and application of pimecrolimus; the drug was safe to be used as a first-line therapy when in fact the drug was only intended to be a second-line therapy; and finally that pimecrolimus was safe for intermittent use when in fact it was not.

108. Despite knowledge of the Sales Representative Defendants to the contrary, they misrepresented information both orally and in writing to healthcare providers, including the Plaintiff's treating physician and Plaintiff, Andrea Perry, herself, about the safety of pimecrolimus. The Sales Representative Defendants intentionally misrepresented pimecrolimus safer then alternative treatments, for the express purposes of having physicians prescribe the product and give out samples to their patients who were diagnosed with the type of disease that pimecrolimus was intended and designed to treat. The Sales Representative Defendants

intentionally misrepresented to healthcare providers, information about the lack of serious health and malignancy risks resulting from the use and application of pimecrolimus, knowing there would be reliance on these misrepresentations in marketing decision to prescribe pimecrolimus for patients, or providing samples of the same.

109. These misrepresentations by the Sales Representative Defendants were material in that they involved statements about the safety and efficacy of pimecrolimus. The Sales Representative Defendants intended treating healthcare providers would rely on these representations which the Sales Representative Defendants knew to be false, or which were made in a reckless manner. In this case, Plaintiffs obtained samples based upon the misrepresentations of the Sales Representative Defendants.

110. As stated above, this omission was material and induced Plaintiffs to use pimecrolimus. If they had been told that pimecrolimus could cause malignancies, they would have been in better position to make a more fully informed decision to use or not use the product.

111. The misrepresentations and omissions set forth above were done with the knowledge that the misrepresentations were false when made.

112. As a direct and proximate result of the intentional misrepresentations as set forth above, Plaintiffs applied pimecrolimus to their infant son which ultimately resulted in injury.

113. As a direct and proximate result of the Sales Representative Defendants' deceit and fraud, Plaintiffs have sustained serious and permanent injuries, including but not limited to, damages, pain and suffering, emotional distress, fear of future diseases, psychological injuries, physical disfigurement, scarring, loss of the enjoyment of life, and risks of reoccurrence of malignancies. Plaintiffs have further incurred medical bills and other healthcare expenses. Plaintiff, Andreas Perry's physical and emotion injuries, serious adverse events and other health

problems proximately caused by the use and application of pimecrolimus, are permanent and continue to compromise, diminish and suppress his natural immune system which exposes him to further health problems, physical ailments, and serious adverse events.

114. In that the injuries suffered by the Plaintiff, Andreas Perry, are continuing in nature, he will continue to suffer, pain, psychological and emotional injuries, physical handicap and permanent injury in the future, will be further compelled to expend great sums of money for medical care and related treatment for said injuries, and will continue to suffer loss or impairment of the capacity for the enjoyment of life.

WHEREFORE, Plaintiffs claim of Defendants, Joe A. Sparks and Mary Gianstasio, compensatory damages, punitive damages, interest and allowable costs of suit.

Count III – Intentional and Negligent Infliction of Emotional Distress Against Novartis Defendants

115. Plaintiffs incorporate herein by reference and re-assert the allegations contained in paragraphs 1-84 above.

116. Novartis Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused Plaintiffs severe emotional distress as set forth in Restatement (Second) of Torts, §46(1) and Bosley v. Andrews, 142 A.2d 263 (Pa. 1958).

117. The conduct of Novartis Defendants in making false statements to the FDA and the general public; knowing the public and physicians would rely on these statements in deciding whether to allow an infant to take pimecrolimus, which Novartis Defendants knew had a highly increased adverse event rate, and which ultimately and directly resulted in Plaintiff, Andreas Perry's lymphoblastic lymphoma; has caused emotional harm to Plaintiffs, Andreas Perry, Andrea Perry and George Perry, and was extreme and outrageous.

118. Plaintiffs have all suffered severe emotional distress as a result of the conduct of Novartis Defendants.

119. Novartis Defendants' actions were willful and/or reckless thus entitling Plaintiffs to punitive damages.

WHEREFORE, Plaintiffs claim of Novartis Defendants, compensatory damages, punitive damages, interest and allowable costs of suit.

Count IV – Breach of Express Warranty (13 Pa. C.S.A. § 2313)
Against Novartis Defendants

120. Plaintiffs incorporate herein by reference and re-assert the allegations contained in paragraphs 1-84 above.

121. Novartis Defendants expressly represented to the users and their physicians that pimecrolimus, was safe and fit for use for the purposes intended, that it was of merchantable quality, and that it did not produce any side-effects dangerous to life, and it was adequately tested and fit for its intended purpose.

122. Members of the medical community in general and Plaintiffs' treating physician in particular, relied upon the representations and warranties of Novartis Defendants for use and application of pimecrolimus, in prescribing, recommending and/or dispensing pimecrolimus.

123. Novartis Defendants knew or should have known that said representations and warranties were false, misleading and untrue in that pimecrolimus was not safe and fit for the use intended, and in fact, produces serious injuries and/or death to the user.

124. As a result of the aforementioned breach of warranties as set forth by 13 Pa. C.S.A. § 2313 by Novartis Defendants, Plaintiff, Andreas Perry, was diagnosed with lymphoblastic lymphoma.

125. As a direct and proximate result of Novartis Defendants' breach of warranty, Plaintiffs have sustained serious and permanent injuries, including but not limited to, damages, pain and suffering, emotional distress, fear of future diseases, psychological injuries, physical disfigurement, scarring, loss of the enjoyment of life, and risks of reoccurrence of malignancies. Plaintiffs have further incurred medical bills and other healthcare expenses. Plaintiff, Andreas Perry's physical and emotion injuries, serious adverse events and other health problems proximately caused by the use and application of pimecrolimus, are permanent and continue to compromise, diminish and suppress his natural immune system which exposes him to further health problems, physical ailments, and serious adverse events.

126. In that the injuries suffered by the Plaintiff, Andreas Perry, are continuing in nature, he will continue to suffer, pain, psychological and emotional injuries, physical handicap and permanent injury in the future, will be further compelled to expend great sums of money for medical care and related treatment for said injuries, and will continue to suffer loss or impairment of the capacity for the enjoyment of life.

WHEREFORE, Plaintiffs claim of Novartis Defendants, compensatory damages, punitive damages, interest and allowable costs of suit.

Count V - Breach of Express Warranty (13 Pa. C.S.A. § 2313)
Against Jae Sparks and Mary Gianstasio

127. Plaintiffs incorporate herein by reference and re-assert the allegations contained in paragraphs 1-84 above.

128. Sales Representative Defendants expressly represented to the users and their physicians that pimecrolimus, was safe and fit for the use for the purposes intended, that it was of merchantable quality, that it did not produce any side-effects dangerous to life, and it was

adequately tested and fit for its intended use.

129. Members of the medical community in general and Plaintiffs' treating physician in particular relied upon the representations and warranties of these Sales Representative Defendants for use and application of pimecrolimus, in prescribing, recommending and/or dispensing pimecrolimus.

130. The Sales Representative Defendants expressly stated to Plaintiffs that pimecrolimus, was safe as a first-line therapy.

131. The Sales Representative Defendants knew or should have known that said representations and warranties were false, misleading and untrue in that pimecrolimus was not safe and fit for the use intended, and, in fact, produces serious injuries and/or death to the user.

132. As a result of the aforementioned breach of warranties as set forth by 13 Pa. C.S.A. § 2313 by the Sales Representative Defendants, Plaintiff, Andreas Perry, was diagnosed with lymphoblastic lymphoma.

133. As a direct and proximate result of Sales Representative Defendants' breach of warranty, Plaintiffs have sustained serious and permanent injuries, including but not limited to, damages, pain and suffering, emotional distress, fear of future diseases, psychological injuries, physical disfigurement, scarring, loss of the enjoyment of life, and risks of reoccurrence of malignancies. Plaintiffs have further incurred medical bills and other healthcare expenses. Plaintiff, Andreas Perry's physical and emotion injuries, serious adverse events and other health problems proximately caused by the use and application of pimecrolimus, are permanent and continue to compromise, diminish and suppress his natural immune system which exposes him to further health problems, physical ailments, and serious adverse events.

134. In that the injuries suffered by the Plaintiff, Andreas Perry, are continuing in

nature, he will continue to suffer, pain, psychological and emotional injuries, physical handicap and permanent injury in the future, will be further compelled to expend great sums of money for medical care and related treatment for said injuries, and will continue to suffer loss or impairment of the capacity for the enjoyment of life.

WHEREFORE, Plaintiffs claim of Defendants, Joe A. Sparks and Mary Gianstasio, compensatory damages, punitive damages, interest and allowable costs of suit.

Count VI – Negligent Failure to Warn
Against Novartis Defendants

135. Plaintiffs incorporate herein by reference and re-assert the allegations contained in paragraphs 1-84 above.

136. Novartis Defendants had a duty to provide adequate warnings with their product pimecrolimus, including in ensure that adequate warnings were provided to healthcare providers, including Plaintiffs' treating physician, concerning the safety and any health risks known or which should have been known resulting from the use and application of pimecrolimus.

137. Novartis Defendants breached their duty by failing to use reasonable care in providing adequate warnings to healthcare providers, including Plaintiffs' treating physician, about the serious adverse health risks caused by pimecrolimus. Specifically, Novartis Defendants failed to adequately warn Plaintiffs or their treating physician there were more severe health risks in their drug then those traditionally used in the treatment of the type of skin disease that Plaintiff, Andreas Perry suffered from; and about the risks of developing malignancies from the use and application of pimecrolimus.

138. Novartis Defendants had knowledge that pimecrolimus, at least as early as 2001, posed serious adverse health risks of malignancies to patients who would use the drug for the

treatment of various skin diseases to which the product was designed to treat. Novartis Defendants failed to warn Plaintiffs or their treating physician of these health risks.

139. Novartis Defendants as the designers, manufactures, distributors and sellers of pimecrolimus were in a superior position to that of Plaintiffs or their treating physician, and other healthcare providers, to have knowledge about these serious adverse health risks posed by pimecrolimus, including the risk of malignancies. Defendants failed to adequately warn Plaintiffs' treating physician so that she could make an appropriate, informed, and independent judgment with respect to what drug to use in the treatment of Plaintiff, Andreas Perry.

140. As a result of Novartis Defendants' failure to adequately warn healthcare providers about the serious health risks posed by their drug, including developing malignancies, Plaintiffs' treating physician gave samples of pimecrolimus to Plaintiff, Andreas Perry.

141. Had Novartis Defendants adequately warned Plaintiffs and/or their treating physician, samples of pimecrolimus would not have been given to Plaintiffs, or Plaintiffs would have been in better position to make a more fully informed decision to use or not use the product.

142. As a direct and proximate result of Novartis Defendants' negligence, Plaintiffs have sustained serious and permanent injuries, including but not limited to, damages, pain and suffering, emotional distress, fear of future diseases, psychological injuries, physical disfigurement, scarring, loss of the enjoyment of life, and risks of reoccurrence of malignancies. Plaintiffs have further incurred medical bills and other healthcare expenses. Plaintiff, Andreas Perry's physical and emotion injuries, serious adverse events and other health problems proximately caused by the use and application of pimecrolimus, are permanent and continue to compromise, diminish and suppress his natural immune system which exposes him to further health problems, physical ailments, and serious adverse events.

143. In that the injuries suffered by the Plaintiff, Andreas Perry, are continuing in nature, he will continue to suffer, pain, psychological and emotional injuries, physical handicap and permanent injury in the future, will be further compelled to expend great sums of money for medical care and related treatment for said injuries, and will continue to suffer loss or impairment of the capacity for the enjoyment of life.

WHEREFORE, Plaintiffs claim of Novartis Defendants, compensatory damages, punitive damages, interest and allowable costs of suit.

Count VII – Negligent Failure to Warn
Against Jae A. Sparks and Mary Gianstasio

236. Plaintiffs incorporate herein by reference and re-assert the allegations contained in paragraphs 1-84 above.

237. Sales Representative Defendants were in the business of marketing, promoting, selling and/or distributing pimecrolimus in the Commonwealth of Pennsylvania.

238. The Sales Representative Defendants had a duty to provide adequate warnings with the product pimecrolimus, including to ensure that adequate warnings were provided to healthcare provides, including Plaintiffs' treating physician, concerning the safety and any health risks known or should have been known resulting from the use and application of pimecrolimus.

239. The Sales Representative Defendants breached their respective duties by failing to use reasonable care in providing adequate warnings to healthcare providers, including Plaintiffs' treating physician, about the serious adverse health risks caused by pimecrolimus. These Sales Representative Defendants failed to adequately warn Plaintiffs and/or their treating physician there were more severe health risks in pimecrolimus products traditionally used in the treatment of the type of skin disease that Plaintiff suffered from, and about the risks of developing

malignancies from the use and application of pimecrolimus.

240. The Sales Representative Defendants had prior knowledge that pimecrolimus posed serious adverse health risks of malignancies to patients who would use and apply pimecrolimus for the treatment of skin disease for which the product was designed to treat.

241. Theses Sales Representative Defendants failed to warn Plaintiffs or their treating physician of the above mentioned health risks. The Sales Representative Defendants as distributors, marketers, and sellers of pimecrolimus were in superior positions to that of Plaintiffs or their treating physician, or other healthcare providers, to have knowledge about these serious adverse health risks posed by pimecrolimus, including the risks of malignancies. The Sales Representative Defendants failed to adequately warn Plaintiffs' treating physician so that she could make an appropriate, informed, and independent judgment with respect to what drugs to use to treat Plaintiff, Andreas Perry.

242. Due to the Sales Representative Defendants respective failures to adequately warn healthcare providers about the serious adverse health risks posed by pimecrolimus, including developing malignancies, Plaintiffs' treating physician gave samples of pimecrolimus to Plaintiffs.

243. Had these Sales Representative Defendants adequately warned Plaintiffs, and/or their treating physician, samples of pimecrolimus would not have been given to them, or Plaintiffs would not have used and applied the product.

244. As a direct and proximate result of Novartis Defendants' negligence, Plaintiffs have sustained serious and permanent injuries, including but not limited to, damages, pain and suffering, emotional distress, fear of future diseases, psychological injuries, physical disfigurement, scarring, loss of the enjoyment of life, and risks of reoccurrence of malignancies.

Plaintiffs have further incurred medical bills and other healthcare expenses. Plaintiff, Andreas Perry's physical and emotion injuries, serious adverse events and other health problems proximately caused by the use and application of pimecrolimus, are permanent and continue to compromise, diminish and suppress his natural immune system which exposes him to further health problems, physical ailments, and serious adverse events.

245. In that the injuries suffered by the Plaintiff, Andreas Perry, are continuing in nature, he will continue to suffer, pain, psychological and emotional injuries, physical handicap and permanent injury in the future, will be further compelled to expend great sums of money for medical care and related treatment for said injuries, and will continue to suffer loss or impairment of the capacity for the enjoyment of life.

WHEREFORE, Plaintiffs, demand as follows:

(1) Judgment for compensatory damages in excess of $75,000 against the Defendants, jointly and/or severally, and for such other amounts as a jury shall find, will fairly and reasonably compensate Plaintiffs for the damages they have sustained;

(2) Judgment for compensatory damages against the Defendants, jointly and/or severally, in amounts in excess of the minimum dollar amount necessary to establish jurisdiction of this Court and for such amounts as a jury shall find will fairly and reasonably compensate Plaintiffs;

(3) Punitive Damages;

(4) Prejudgment interest from the date of injury or filing of this action until paid;

(5) Interest at the rate of 12 percent per annum from the date of judgment until paid;

(6) Trial by jury;

(7) Attorneys' fees and costs herein incurred; and

(8) Any and all further proper relief to which they may appear to be entitled

Respectfully submitted,

LAW OFFICE OF LARRY M. ROTH, P.A.

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CERTIFICATE OF SERVICE

I certify that on the _2__ day of _August_, 2006 the foregoing document was electronically filed with the Court and is available for viewing and downloading from the Court's ECF system. The document was also served on all counsel of record in accordance with the Federal Rules of Civil Procedure and Local Rules for the Eastern District of Pennsylvania as indicated below:

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